

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES, *et al.*, *ex rel.* ADAM WITKIN,)

Plaintiffs,

V.

MEDTRONIC, INC, *et al.*,

Defendants.

No. 1:11-cv-10790-DPW

STATEMENT OF INTEREST

The United States submits this brief statement of interest to address the parties’ recent filings concerning supplemental authority on the application of the False Claims Act, 31 U.S.C. § 3729, to cases involving violations of the anti-kickback statute (“AKS”), 42 U.S.C. § 1320a-7b(b)(2). *See* Dkt. Nos. 233 and 234. The recent filings do not cite the controlling First Circuit precedent in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), where the court noted that “[w]e have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party.” *Id.* at 390; *see also id.* at 393 (rejecting defendant’s argument that the claims “were not false or fraudulent because [they] were for services that would have been provided in the absence of the alleged AKS violations”). In 2010, Congress confirmed that a kickback renders any resulting claims false or fraudulent. *See* 42 U.S.C. 42 U.S.C. § 1320a-7b(g).

Thus, when a medical device company or other entity pays a kickback with an intent to induce a health care provider to submit a claim that seeks reimbursement for the entity's product, that entity *causes* the submission of a false claim and violates 31 U.S.C. § 3729(a)(1)(A), even where the submitting provider has no knowledge of the kickback or culpability under either the

AKS or False Claims Act. Contrary to the suggestions in the recent filings, then, neither the government nor a relator acting on behalf of the government need show that the defendant's conduct was "a substantial factor in inducing providers to submit claims for reimbursement." Dkt. 234 at 2; Dkt. 233 at 1-2. Such a standard would suggest that the plaintiff in an AKS-predicate False Claims Act case must show that the kickback corrupted the judgment of, or otherwise influenced, the provider's decision to submit a claim. Numerous courts have rejected that approach. For example, in *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019), the court rejected Teva's argument that "the 'substantial factor' standard incorporates 'but for' causation, as a principle of tort law, and therefore requires that the kickback have actually caused a speaker to prescribe a Teva drug." *Id.* at *26. The *Teva* court observed that "[r]eading the FCA in the manner Defendants propose would effectively render 'but for' prescribing a legal prerequisite in 'cause to be presented' AKS cases, but not in cases where the defendant itself presents the claims to the Government." *Id.* Instead, the *Teva* court held that "a plaintiff in an AKS/FCA legal falsity case satisfies his burden of production for causation by showing that a physician referred or recommended a patient to a provider after receiving an illegal payment from that provider." *Id.* Courts in this District have taken the same approach. See *United States v. Regeneron Pharms., Inc.*, No. 20-11217-FDS, 2020 U.S. Dist. LEXIS 227643, at *33 (D. Mass. Dec. 4, 2020) (holding that the government need not plead "that the kickbacks actually corrupted clinical decision-making or provide 'proof that the underlying medical care would not have been provided but for a kickback'" (quoting *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018))); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) (holding that, in a False Claims Act case involving alleged kickbacks by a

pharmaceutical company to physicians, “[i]t is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback”).

These decisions make sense in light of the Congressional design of the AKS, which covers not only those situations in which a kickback *in fact* corrupted a provider’s medical judgment, but also those in which *the possibility* exists that the provider’s judgment could be corrupted. Given the difficulty in discerning whether a kickback actually corrupted a provider’s judgment, and in order to guard against the potential for such corruption, the AKS penalizes *offering*, not just paying, an inducement. *See* 42 U.S.C. § 1320a-7b(b)(2). That is, the AKS itself does not require the type of causation the defendant suggests; it does not even require the government to show the offeree accepted the remuneration. Similarly, pursuant to the False Claims Act, claims resulting from kickbacks are *per se* false, regardless of whether the kickback actually influenced the provider’s decision-making. 42 U.S.C. § 1320a-7b(g); *see also Greenfield*, 880 F.3d at 97 (rejecting defendant’s contention that a False Claims Act “plaintiff would have to prove a kickback actually influenced a patient’s or medical professional’s judgment”). Put differently, if an entity pays a kickback with the intent to cause the submission of a claim and then a claim is in fact submitted (including by an innocent third-party), the payor of the kickback has caused the presentation of a false claim.

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Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

NATHANIEL R. MENDELL
Acting United States Attorney

/s/ Gregg Shapiro
GREGG SHAPIRO
Assistant United States Attorney
United States Attorney's Office
One Courthouse Way, Suite 9200
Boston, MA 02210
Phone: (617) 748-3366
gregg.shapiro@usdoj.gov

JAMIE ANN YAVELBERG
HOLLY H. SNOW
Attorneys, Civil Division
United States Department of Justice
175 N Street, N.E.
Washington, DC 20002
Phone: (202) 616-2879
holly.h.snow@usdoj.gov